

## EXHIBIT 401

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# **Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances**

**Friday, November 14, 2008  
1:00 – 2:30 PM (ET)**

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# Question and Answer Period

**Please type your questions** into the **QUESTIONS** box located on the lower left-hand side of the screen.

Click the **SEND** button when you are ready to submit your question.

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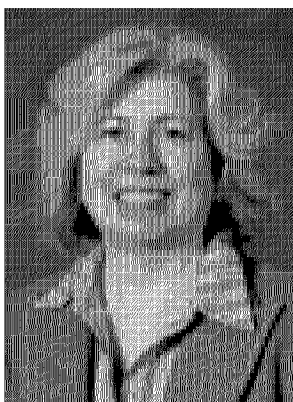
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# Webinar Overview



**Anita T. Ducca**  
**Senior Director, Regulatory Affairs**  
**HDMA**

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# Objectives

- Why HDMA and Members prepared the *Industry Compliance Guidelines* (ICG)
- Discuss DEA's concerns & points for distributors
- DEA actions
- HDMA interaction with DEA
- Legal authority
- "Walk through" the *Industry Compliance Guidelines* & DEA's reaction
- Q & A

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# Poll Question #1

**Would those who are listening in please indicate your key responsibility within your company?**

- A. Sales/Trade Representative
- B. Customer Service/Relations
- C. Operations/Warehouse staff
- D. Regulatory/Compliance
- E. Government Relations
- F. Other

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# History/Background

- Over last 2+ yrs –
  - DEA meetings with distributors
  - Discuss DEA expectations
- Apparent change in these expectations, e.g., traditional “reporting” no longer adequate
- Intensity stepped up
  - 3 DEA letters
  - Suspended distributor registrations

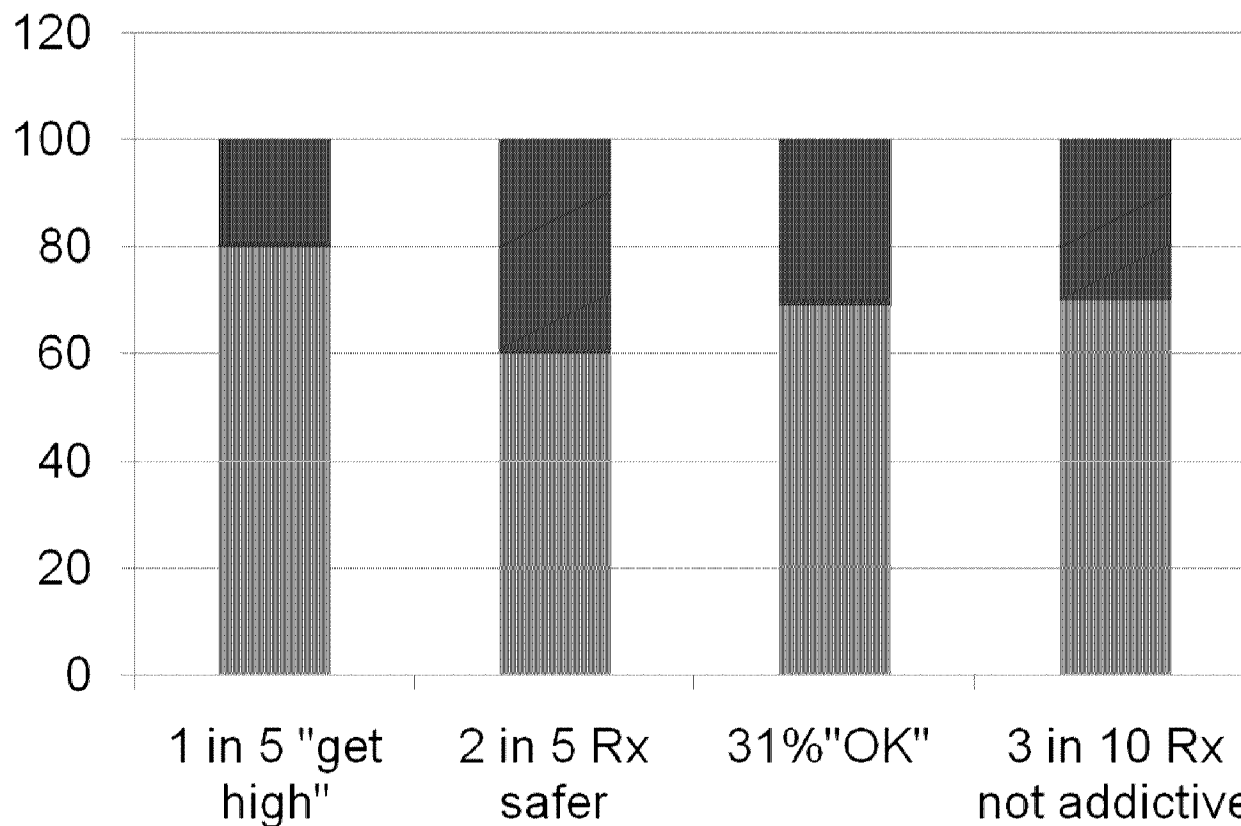
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# What is Driving DEA: Rx Drug Abuse

- Increase in prescribing for pain, e.g., between 1999 and 2002
  - Oxycodone Rx ↑ 50%
  - Morphine Rx ↑ 60%
- Non-medical Rx drug abuse ↑ ~ 80 % from 2000 (3.8 million); 2nd only to marijuana abuse
- Ease of Internet purchasing

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# Teens' Views on Rx Drug Abuse



SOURCE: 2005 Partnership Attitude and Tracking Study (PATs)  
Released April 2006

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# Joseph Rannazzisi

## Deputy Assistant Administrator, DEA

### Congressional Testimony - 5/16/07

DEA began an **Internet Distributor Initiative**  
... because...

the seller has a **legal obligation** to ensure the substances  
transferred are **not destined for diversion**...

DEA's educational presentation ... is designed to emphasize  
to wholesalers their obligation **not** to sell where diversion  
appears to be occurring **or** face the **loss of their DEA**  
**registration** or judicial sanctions.

(emphasis supplied)

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# DEA Points for Wholesale Distributors

- Registrant cannot rely on customer's DEA registration and state licensure
- DEA cannot tell a distributor if order is legitimate
- Distributor must
  - decide which orders are suspicious
  - make a sales/shipment decision
- Distributors selling CSs being dispensed outside the course of professional practice must stop immediately

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# Concerns About the DEA Distributor Meetings and Guidance

- Guidance was:
  - Ambiguous
  - Inconsistent, e.g., DEA HQ and field staff
  - Inappropriate for distributors
- Unable to rely on DEA registration/state licensure
- Changing emphasis on distributor responsibility:
  - “know your customer”
  - identify, stop shipment and report “suspicious orders”

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# Enhanced Communications Between HDMA and DEA

To support our members, HDMA worked to:

- Initiated development of an “Industry Compliance Guideline” with our members
- Established a dialogue with the DEA’s Chief Counsel’s Office & Office of Diversion Control

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# Purpose of ICG and DEA Communications

- Demonstrate our members' commitment
- Distributors part of the solution
- Address urgent needs:
  - Clarify DEA expectations
  - “Educate” DEA
  - Gain consistency in DEA guidance
- “Head-off” further enforcement or regulatory action

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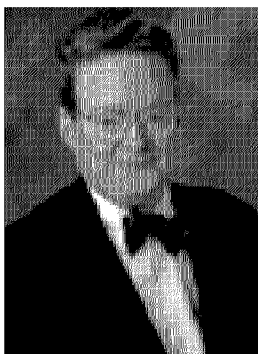


# Considerations in Developing the ICG

- Must be “robust and adaptable”
- Robust:
  - Rigorous enough to reliably help identify potential problem areas
  - Address DEA compliance expectations
- Adaptable:
  - Can change as criminals modify diversion practices
  - Differing distributor business models
  - Can change with DEA regulatory changes

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# Presentation by:



**David L. Durkin, Esq.**  
**Principal**  
**Olsson Frank Weeda**  
**Terman Bode Matz PC**



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# Preface

- This presentation is for general informational purposes only. It is not intended to and does not constitute legal advice. Please contact your attorneys if you need legal advice.
- The views expressed in this presentation do not necessarily reflect the views of HDMA, its members, or any particular client of OFW.

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# **Industry Compliance Guidelines: Reporting Suspicious Orders And Preventing Diversion Of Controlled Substances**

- Rationale for Industry Compliance Guidelines (ICG)
- ICG Structure and Implementation
- DEA Interaction and Moving Forward

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## Poll Question #2

**What does the DEA expect from Distributors with regard to Suspicious Orders? (check all that apply)**

- A. Monthly reports of excessive purchases
- B. A report for each order that is an unusual size or otherwise deviates substantially from the customer's normal pattern
- C. Only fill orders of customers when you know who the customer's customers are
- D. Stop the entire order for the specific drug code product if it may meet the SO criteria
- E. Stop a customer's order for all CS products if any one part of the order is unusual
- F. The sun, the moon and the stars
- G. All of the above

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# Statutory Framework: Conditions of Registration

- CSA section 303: Registration permitted if consistent with the “public interest” and international agreements
- First factor in determining the “public interest”:  
“maintenance of effective controls against diversion . . . into other than legitimate . . . channels”

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# Regulatory Implementation

## CSA section 301

- DEA may promulgate and enforce any rules, regulations or procedures relating to registration and control of manufacture or distribution of controlled substances

## 21 CFR § 1301.74(b)

- Design and operate a system to *disclose* to the registrant suspicious orders of controlled substances
- Inform the local DEA office “when discovered”
- “Suspicious orders include orders of *unusual* size, deviating substantially from a *normal pattern*, and orders of *unusual* frequency.”

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# Security Requirements

- “All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.” 21 C.F.R. 1301.71(a)
- “In evaluating the overall security system of a registrant or applicant, the Administrator may consider . . . The adequacy of the registrant’s or applicant’s system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations” *Id.* at 1301.71(b)(14)

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# **“Suspicious Order” Criteria: Anecdotal Advice from DEA**

- Quantities of drugs purchased
- % of controlled versus noncontrolled
- Size of orders
- Location of customer
- Only current drugs of concern
- No established business credit
- Frequent large orders

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## Poll Question #3

**“Controlling diversion” means:**

- A. Ensuring there is no theft, loss, or shrink from your distribution facility;
- B. Ensuring that pharmacies, doctors, and clinics do not dispense to persons who will use the CS for illicit purposes; or
- C. Both

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# What Has Changed?

## September 27, 2006 Letter

- Reporting a suspicious order does not relieve the distributor of the responsibility to maintain effective controls against diversion
- Registrant *cannot* rely on customer's DEA registration and state licensure
- Apparent emphasis on "internet pharmacies"

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# What Has Changed?

## December 27, 2007 Letter

- Deviation from “normal pattern” is not only determined by order size
- “Suspicious” nature of order depends not on pattern of ordering customer, but on patterns of registrant’s *customer’s base* and patterns “throughout . . . the regulated industry.”
- “Rigid formulas” may be insufficient

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## December 27, 2007 Letter (con't)

- “Registrants must conduct an independent analysis of suspicious orders prior to completing a sale”
- “Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, *or should have known*, that the controlled substance were being diverted.” (emphasis supplied)

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# ICG Development

- HDMA Regulatory Affairs Committee
- Reviewed by counsel
- Outreach to related interest groups
- Executive Committee approval
- Presentation to DEA April 15, 2008
- Follow-up DEA Meeting June 4, 2008
- Final DEA Meeting September 5, 2008
- DEA commendation letter – October 23, 2008

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# Meetings with DEA

- Chief Counsel's Office
- Senior Office of Diversion Control officials
- Purpose:
  - Demonstrate industry commitment,
  - Clarify requirements for distributors, and
  - Seek DEA "Imprimatur"

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# Guidance Should . . .

- Address DEA Expectations to:
  - “Know your customer”
  - Maintain a “system”
  - Stop shipments (while being examined)
- Reduce HDMA members’ compliance risk
- Identify orders that are truly of concern (minimize “false alarms”)

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# ICG At-a-Glance

## Introduction

- Distributors' role; purpose of the ICG
- History and general legal requirements
- Distributor's commitment to preventing diversion

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# ICG At-a-Glance

## I. Know Your Customer Due Diligence

- Information Gathering & Review
  - types of Rx & prescribers,
  - % of CS,
  - Internet business activities,
  - prior DEA/state audits
- Independent Investigation
- Confirmation with local DEA office, state BOP
- Internet search

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# ICG At-a-Glance

## II. Monitoring for SO's

- System design
  - Electronic system; written SOPs; assign responsibilities
- Identify Product & Customer Characteristics
  - establish groups or “families” of drugs based on class of trade &/or product
  - Contact with DEA field offices and nationwide sources to be alert to changing “Drugs of Concern”  
[http://www.dea diversion.usdoj.gov/drugs\\_concern/index.html](http://www.dea diversion.usdoj.gov/drugs_concern/index.html)

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# ICG At-a-Glance

## II. Monitoring for SO's *Change the Language*

- “Orders of Interest” vs. “Suspicious Orders”
- Examine possibility of mistake
- Prevent over-reporting
- Provide more meaningful reporting to DEA

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# ICG At-a-Glance

## II. Monitoring for SO's

- Develop “Thresholds” To Identify “Orders of Interest”
  - Calculate “average” orders for “families”
  - Identify orders of “unusual” size/frequency/pattern
  - Cumulative orders
- Other circumstances that warrant follow-up inquiry to determine if “suspicious”
  - New information on drugs of concern
  - Recent DEA enforcement activity

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# ICG At-a-Glance

## III. Suspend/Stop An Order Of Interest

If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor ***should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.***

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# ICG At-a-Glance

## IV. Investigation of Orders of Interest

- Initial Review – Why did it trigger a threshold? Error? Change in customer business?
- Investigate the Order – If initial review inconclusive, perform a more intensive review, e.g., prior orders, interview customer, verify customer input
- Seek additional information

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# ICG At-a-Glance

## IV. Investigation of Orders of Interest (Con't)

- Documentation -- Names, titles, dates, other; keep copies of written information
- Flexible SOPs
- Evaluate future customer orders/relations in light of reportable “suspicious order”
- Assumes order is on hold while under review

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# ICG At-a-Glance

## V. File Suspicious Order Report

- Immediately report to DEA by phone – (see 21 CFR § 1301.74(b))
- Report even if all circumstances unclear, e.g., not yet a customer, but gives information on intentions
- Timeliness crucial
- Written follow-up strongly recommended
- Documentation

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# ICG At-a-Glance

## VI. Employees, Training & SOPs

- Review DEA regulations; cover firm's compliance steps
- Expand staff training, e.g., operations, customer service and sales, those filling orders
- SOP review and revision minder

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# ICG At-a-Glance

## VII. Additional Recommendations

- Periodic audits
- Review/revise SOPs, monitoring systems, training
- Update customer records

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# DEA Reaction

- Initially - Only one question: Please clarify “what is stopped [when a threshold is exceeded]?”
- Acknowledgement that DEA retains full enforcement discretion
- Overall, very favorable reaction

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# Additional Points

- The ICG is ***not*** an industry standard
- HDMA will not “enforce” the ICG
- DEA will “enforce” -- even if following the ICG
- Distributors are ***not*** deputized criminal investigators

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## **Poll Question #4A – 2 Questions**

**A) Has your company either revised their Suspicious Order Monitoring systems and SOPs or initiated substantial efforts to revise them within the past year?**

- A) Yes
- B) No
- C) Don't know

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## **Poll Question #4B**

**B) If “Yes” to the previous question, have you used the ICG to help develop your revisions?**

- A) Yes
- B) No
- C) Don't know

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# ***What Does the ICG Mean for Me?***

- Robust procedures will have two positive effects:
  - Actual decrease in diversion
  - Defensible position in the event of investigation

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# Wrap-Up

- HDMA fully recognizes that much is expected
- Based on DEA input
- DEA's concerns continue - enhanced regulatory climate likely
- Prepared by making strong headway in constructive dialogue with agency

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# Question and Answer Period

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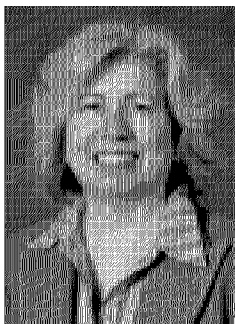
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# Conclusion

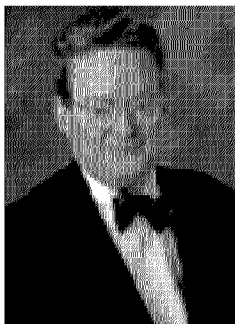
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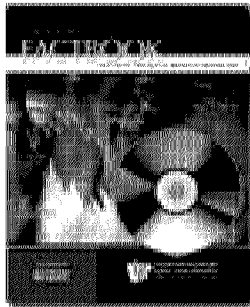
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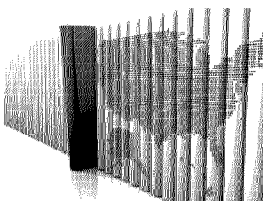
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